APR 19 2013

510(K) Summary

I. SUBMITTER NAME & ADDRESSS: Medtronic Sofamor Danek USA, Inc
1800 Pyramid Place
Memphis, Tennessee 38132
Telephone: (901) 396-3133
Fax: (901) 346-9738
Establishment Registration: 1030489

CONTACT PERSON: Ryan Massey
Principal Regulatory Affairs Specialist

DATE PREPARED: February 8, 2013

II. PROPOSED PROPRIETARY TRADE NAME: MASTERGRAFT® Strip
MASTERGRAFT® UltraMatrix

DEVICE CLASSIFICATION NAME: Resorbable Calcium Salt Bone Void Filler
REGULATION NUMBER: 21 CFR 888.3045
CLASSIFICATION PRODUCT CODE: MQV
CLASS: II

III. IDENTIFICATION OF LEGALLY MARKETED DEVICES:
MASTERGRAFT® Strip K082166 (S.E. 06/02/2009)

IV. DEVICE DESCRIPTION:
MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix consist of a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic. In the MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix devices, the collagen is a highly purified (>95%) Type I bioresorbable lyophilized collagen. The

biphasic ceramic portion of MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix is provided in a 15 percent hydroxyapatite and 85 percent β-tricalcium phosphate formulation.

MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix are supplied sterile in a premixed strip form for single patient use.

MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix devices are biocompatible, osteoconductive, porous implants that allow for bony ingrowth across the graft site while resorbing at a rate consistent with bone healing. The devices readily absorbs bone marrow aspirate and had been shown to heal bone defects.

The purpose of this Special 510(k) application is to add additional sizes (known as MASTERGRAFT® UltraMatrix 5cc, 10cc, and 20cc) to the previously cleared MASTERGRAFT® Strip product family. The sizes proposed in this Special 510(k) were part of the original product design for MASTERGRAFT® Strip device, and were included in the design verification and validation activities reported in K082166.

V. INDICATIONS FOR USE:

MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix are to be combined with autogenous bone marrow and is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.

The device is to be gently packed into bony voids or gaps of the skeletal system (i.e., the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

VI. SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS:

Comparison Feature	**Subject MASTERGRAFT® UltraMatrix**	**Predicate MASTERGRAFT® Strip**
Indication for Use	Identical	K082166 (S.E. 06/02/2009)
Fundamental Scientific Technology • Operating Principle • Mechanism of Action	Identical	K082166 (S.E. 06/02/2009)
Basic Design	Identical	K082166 (S.E. 06/02/2009)
Performance	Identical	K082166 (S.E. 06/02/2009)
Manufacturing principles	Identical	K082166 (S.E. 06/02/2009)
Sterilization	Identical	K082166 (S.E. 06/02/2009)
Shelf-Life	Identical	K082166 (S.E. 06/02/2009)
Packaging	Identical	K082166 (S.E. 06/02/2009)
Material Composition • Collagen • Granules	Identical	K082166 (S.E. 06/02/2009)
Use of rigid fixation	Identical	K082166 (S.E. 06/02/2009)
Safety and Effectiveness profile	Identical	K082166 (S.E. 06/02/2009)
Size	5cc Product Length: 4.7 cm ± 0.5 cm Width: 1.0 cm ± 0.3 cm Thickness: 1.1 cm ± 0.3 cm 10cc Product (2 x 5cc) Length: 4.7 cm ± 0.5 cm Width: 1.0 cm ± 0.3 cm Thickness: 1.1 cm ± 0.3 cm 20cc Product Length: 4.7 cm ± 0.5 cm Width: 1.9 cm ± 0.4 cmThickness: 1.1 cm ± 0.3 cm	12cc Product Length: 10.0cm +/- 0.5cm Width: 2.0cm +/- 0.3cm Thickness: 0.6cm +/- 0.2cm 43cc Product Length: 36.0cm +/- 1.0cm Width: 2.0CM +/- 0.3cm Thickness: 0.6cm +/- 0.2cm

VII. DISCUSSION OF NON-CLINICAL TESTING:

Non-clinical testing was performed in accordance with FDA Recognized Consensus Standards and FDA Guidelines wherever they are applicable. Data to support these rationales are provided to demonstrate that the subject devices are substantially equivalent to the predicate device.

Previously submitted non-clinical testing was performed in accordance with the following standards:

- ASTM F1185-03: 2009, Specification for Composition of Ceramic Hydroxyapatite for Surgical Implants
- ASTM F1088-04a: 2010, Specification for β-tricalcium Phosphate for Surgical Implantation
- ISO 22442-1: Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices -- Part 1 Analysis and Risk Management
- ISO 22442-2: Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices -- Part 2 Controls on Sourcing, Collection, and Handling
- ISO 22442-3: Animal Tissues and Their Derivatives Utilized in the Manufacture of Medical Devices -- Part 3 Validation of the Elimination and/or Inactivation of Virus and Transmissible Agents
- ISO 10993-3: 2003/(R) 2009, Biological evaluation of medical devices -- Part 3 Tests for genotoxicity, carcinogenicity, and reproductive toxicity. (Biocompatibility)
- ISO10993-4: 2009, Biological evaluation of medical devices -- Part 4: Selection of tests for interactions with blood
- ISO 10993-5: 2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity. (Biocompatibility)
- ISO 10993-6: 2007, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation. (Biocompatibility)

- ISO 10993-10: 2010, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization. (Biocompatibility)
- ISO 10993-11: 2006, Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity. (Biocompatibility)
- ISO 10993-12: 2008, Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials. (Biocompatibility)

VIII. CONCLUSION:

Documentation provided in this submission demonstrates that the subject device is substantially equivalent to the previously cleared bone void filler MASTERGRAFT® Strip (K082166, SE 06/02/2009).

The subject device is substantially equivalent to predicate MASTERGRAFT® Strip in several categories including: indication, material composition (including biphasic calcium phosphate granules and collagen), biodegradability, sterility, shelf-life, need for rigid fixation, biocompatibility and the ability to resorb during the healing process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Sofamor Danek USA, Incorporated
% Mr. Ryan Massey
Principal Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Letter dated: April 19, 2013

Re: K130335
Trade/Device Name: MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: March 20, 2013
Received: March 22, 2013

Dear Mr. Massey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix

Indications for Use:

MASTERGRAFT® Strip and MASTERGRAFT® UltraMatrix are to be combined with autogenous bone marrow and are indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure and can be used as a bone graft extender.

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130335